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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/282,239	03/31/1999	STEVEN A. GOLDMAN	19603/1426	8339

7590 06/12/2007
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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06/12/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/282,239

Applicant(s)

GOLDMAN ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25,26 and 29-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25,26 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/28/2007 has been entered.

Applicant's amendment of claims 25, 26 and 29 and the addition of new claims 30-41, in the paper of 3/28/2007, is acknowledged. Claims 25, 26 and 29-41 remain at issue and are present for examination.

Applicants' arguments filed on 3/28/2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 25, 26, 29-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 26, 29-41 are indefinite in that the recitation of "An enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, the majority of which mature into oligodendrocytes" is unclear as to its meaning. It is unclear as to the meaning of or whether "the majority of which mature into oligodendrocytes" refers to the claimed "preparation of oligodendrocyte progenitor cells" or to the "mitotic oligodendrocyte progenitor cells" themselves. With respect to the indefiniteness regarding the meaning of "the majority of which mature into oligodendrocytes" it is further unclear as to whether such a limitation requires specific culture conditions or whether this limitation is independent of any culture conditions.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 29-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Claims 25, 26, 29-41 are rejected under this statute because the newly added recitation of "the majority of which mature into oligodendrocytes" is not supported by applicants specification at the time of filing and is thus considered new matter.

Applicants statement of support at page 5, lines 17-22; page 7, lines 12-18; page 13, lines 30-32; page 11, lines 10-13; page 20, lines 11-15; page 21, lines 21-25; page 22, lines 11-12; page 23, lines 13-15 and 18-22; and Figure 4, as well as the rest of applicants specification has been considered, however, it remains that support for this newly amended recitation and the claimed genus of cells could not be found (See also above 112 second paragraph rejection).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25, 26 and 29-41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al. (U.S. Patent No. 6,361,996 B1).

This rejection which was stated in the previous office action, and applicants filing of an appeal brief and the examiner's filing of an examiner's answer are noted. It is

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further noted that after the filing of the examiner's answer, applicants have filed a request for continued examination and further amended claims 25, 26 and 29 and added new claims 30-41, in the paper of 3/28/2007 and applicants traverse the rejection as it applies to the newly amended claims.

For applicants convenience the original rejection is repeated herein:

Rao et al. teach an isolated, pure (enriched or purified) and homogeneous population of lineage-restricted oligodendrocyte-astrocyte precursor cells which are capable of self-renewal and differentiation into oligodendrocytes and astrocytes and methods of generating, isolating and culturing such oligodendrocyte-astrocyte precursor cells. The specific pure homogeneous population of cells isolated by Rao et al. is illustrated in Figure 1 (See specifically cell type -14, and the supporting text) and while Rao et al. specifically teach as an example said pure (enriched or purified) homogeneous preparation of cells as isolated from rat, Rao et al. point out that the invention encompasses all mammalian neuroepithelial stem cells and is not limited to neuroepithelial stem cells from the rat. Mammalian neuroepithelial stem cells can be isolated from human and non-human primates, equines, canines, felines, bovines, porcines, ovines, lagomorphs, and the like. Thus, Rao et al. anticipates those claims to an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, the majority of which mature into oligodendrocytes, wherein an oligodendrocyte specific promoter (CNP2) is transcriptionally active in the oligodendrocyte progenitor cells..

The preparation taught by Rao is such that a cyclic nucleotide phosphodiesterase 2 promoter is inherently transcriptionally active in all cells of the

enriched or purified preparation. This is evidenced by the reference Scherer et al. (Neuron Vol 12, pp 1363-1375, June 1994, see applicants IDS) who teach the differential cellular and temporal regulation of the 2',3'-cyclic nucleotide 3'-phosphodiesterase gene (CNP) and teach that the 2',3'-cyclic nucleotide 3'-phosphodiesterase II promoter is transcriptionally active in oligodendrocytes, Schwann cells and many additional tissues and appears before the appearance of mature oligodendrocytes, in oligodendrocyte precursor cells early in brain development (See page 1365-1367, Figures 4 and 5 and supporting text).

Claims 25, 26 and 30, which are drawn to the preparation of oligodendrocyte progenitor cells of claim 29 are included in this rejection because these product-by-process like limitations ("from a post-natal human" for claim 25 and "from an adult human" for claim 26, fetal human) do not change the oligodendrocyte progenitor cells of claim 29. Rao further teaches that a better understanding of a number of tumors and other diseases in humans could be facilitated by a better understanding of these cell types and the ability to isolate and grow these mammalian cells *in vitro*, which allows for the possibility of using such stem cells to treat neurological disorders in mammals, particularly humans. Further, such mammalian neuroepithelial stem cells can be used therapeutically for treatment of certain diseases, e.g. Parkinson's Disease, such as by transplantation of such cells into an afflicted individual. Moreover, such cells can still further be used for the discovery of genes and drugs that are useful for treating certain of these diseases.

One of ordinary skill in the art at the time of filing would have been motivated to use the methods taught by Rao et al. to isolate an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells from humans so that these pure cell preparations could be used to treat neurological disorders in humans, such as Parkinson's Disease, such as by transplantation of such cells into an afflicted individual. This motivation is suggested by Rao et al. and the reasonable expectation of success comes from the results of Rao et al. who successfully isolated such an enriched or purified preparation of mitotic oligodendrocyte progenitor cells from rat.

Applicants traverse this rejection as it applies to applicant's newly amended and added claims on the following basis. Applicants continue to traverse this rejection by summarizing applicant's interpretation of the various teachings of Rao et al. (the 996' patent). Applicants submit that the 996' patent discloses multipotential neuroepithelial stem cells and lineage-restricted astrocyte/oligodendrocyte precursor cells. Applicants submit that these cells are capable of self-renewal as well as further differentiating into oligodendrocytes 58, type 1 astrocytes 62, and type 2 astrocytes 66 and applicants reference the cells and experiments of examples 14 and 15 in making applicants point that the 996' patent's astrocyte/oligodendrocyte progenitor cells have a bias to differentiate to astrocytes and this clearly distinguishes them from the presently claimed oligodendrocyte progenitor cells, the majority of which mature into oligodendrocytes. After making this point applicants continue to submit that there exist multiple pathways to generate post-mitotic, mature oligodendrocytes and reference numerous artisans in the field and their published results. Based upon these "multiple pathways" as

submitted by applicants, applicants submit that there is no reason to believe as the previous office action have suggested, that the 996' patent inherently produces another precursor which has the claimed characteristics.

Supporting this applicants further submit that the previous Examiner's answer states the claims are anticipated by Examples 7 and 15 of the 996' patent, as these examples must produce an intermediate between the 996' patent's oligodendrocyte-astrocyte precursor cells and the fully differentiated cells. Applicants disagree with this position on the basis that these firstly these examples involve work with rat cells not human cells and that the mere mention of cells that have a different morphology than oligodendrocyte type-2 astrocyte progenitor cells is entirely speculative and contrary to what Dr4. Rao said in his second declaration.

Applicants complete argument and amendment of the claims, continues to be acknowledged and has been carefully considered, however, continues to be found nonpersuasive for the reasons previously made of record in the previous office actions and the previous examiners answer.

It continues that applicants claims to "an enriched or purified preparation of human mitotic oligodendrocyte progenitor cells, "the majority of which mature into oligodendrocytes..." are interpreted broadly as is reasonable such that "the majority of which mature into oligodendrocytes" refers to the claimed "mitotic oligodendrocyte progenitor cells" themselves (See above 112 second paragraph rejection). Thus applicants argued points that the referred to preparations of cells of the 996' patent as taught in Examples 14 and 15, do not anticipate the instant claims because these

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recited preparations resulted in more "non-oligodendrocyte cell types" than "oligodendrocyte cell types" is irrelevant to the limitations of the claims.

Further, if one was to interpret that "the majority of which mature into oligodendrocytes" refers to the claimed "preparation" and not to the cells themselves, it remains that the progenitor cells of Examples 14 and 15 of the 996' patent would still anticipate the claimed preparations of cells on the basis that applicants have not stipulated under what conditions the progenitor cells of the preparation mature into their progeny. As is made clear by applicants presented references suggesting multiple pathways of development for oligodendrocytes and by the 996' patent itself, given the various experimental protocols used to treat the various cell preparations, the course of development of a progenitor cells is highly dependent upon many factors, including the signaling molecules a progenitor cells is exposed to as well as the conditions under which this exposure takes place. For these reasons it remains that the preparations taught by Rao et al. continue to anticipate the claimed preparations of progenitor cells because it continues to be the position that the progenitor cell preparations taught by Rao et al. anticipate the claimed cell preparations.

Claims 30, 34, 38 and 39 and 40 which require that the progenitor cell is from a fetal human are included in this rejection for the reasons discussed previously that it continues to be understood that the source of the progenitor cell is irrelevant to distinguishing the claimed preparation of progenitor cells (i.e. fetal vs. post natal vs. adult origin).

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Claims 29, 31-34 and 35-38 are included in the rejection because the preparations of cells taught by Rao et al., referenced above and previously, as taught by Rao et al., as discussed previously and above, express A2B5 antigen and do not express O4 antigen, GFAP antigen and β III tubulin antigen (See example 15).

For these reasons, claims 25, 26 and 29-41 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rao et al. (U.S. Patent No. 6,361,996 B1).

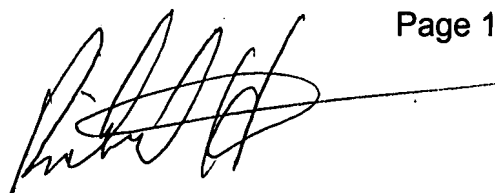
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

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A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
6/5/2007